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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,218	08/16/2000	Miroslav Colic	4904-4	3341

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/640,218

Applicant(s)
Colic, M.

Examiner
Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 16, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) 3-8 and 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This application filed August 16, 2000, claims benefit to provisional application 60/149,131, filed August 16, 1999.

Applicants' amendment filed January 16, 2003, paper number 7, has been received and entered. The specification has been amended. Claims 1, 2, 9 and 10 have been amended. Claims 1-14 are pending.

Election/Restriction

Applicant's election of Group I, claims 1, 2, 9 and 10, in Paper No. 5 was acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election was treated as an election without traverse (MPEP § 818.03(a)). No further arguments are presented in the present amendment.

Claims 1-14 are pending. Claims 3-8 and 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1, 2, 9 and 10 as directed to a pharmaceutical composition encompassing a silica containing solid containing silica with no additional components, are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims drawn to a nonelected invention . A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144).

Priority

Applicant has complied with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e). Specifically, the amendment to the specification in which the claim of benefit of an earlier application in the first sentence of the specification has been made (37 CFR 1.78(a)(2)).

Information Disclosure Statement

it is noted that the listing of references in the specification is not a proper information disclosure statement. See for example pages 10 and 12 of the instant specification. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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Claim objections

Claim 9 objected to for a typographical error is withdrawn. Amendments to the claims has obviated the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, claim 1 has been amended to encompass a 'silicate in crystalline or semicrystalline form' however a review of the portions of the specification pointed to by Applicants for support of this amendment indicates that there is no support for 'semicrystalline form'. The specification provides no literal support for this embodiment and fails to provide figurative support in defining

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the specific nature of what would be considered semicrystalline. Further, there is no specific support for using one specific form of silicate over another in the instantly claimed composition

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1, 2, 9 and 10 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Initially, the amendments to the claims has obviated the basis of each of the previous rejections of record.

Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the metes and bounds of the term 'semicrystalline' recited in claim 1 are unclear and indefinite. The term semicrystalline is not specifically defined in the instant specification, and the amount of crystalline structure required or encompassed by the claim is not clearly set forth by use of this term. The dependent claims are included in the basis of the rejection because they encompass this embodiment and fail to further clarify the metes and bounds of the term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Dorn *et al.*

(US Patent 4,927,750) is withdrawn.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bollon *et al.*

(US Patent 4,029,631) as evidenced by Dorn (US Patent 4,927,750) and Dorn *et al.* (US Patent 4,927,750) is withdrawn.

Amendments to the claims has differentiated the instantly claimed invention from that disclosed by Dorn *et al.* and Bollon *et al.*

Newly amended claims 1, 2, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Marler *et al.* (US Patent 5,147,838).

Claim 1 is drawn to a composition comprising silica having an average size of 6 microns or less, dependent claims 2 define possible types of silica and dependent claim 9 is a silica composition which does not contain aluminum. Marler *et al.* describe a composition comprising porous crystalline silicates (column 1, lines 17-20). The particle size produced by the methods described by Marler *et al.* produces crystals of about 1 to a bout 2 microns (column 3, lines 65-67) and can be made from a variety of materials containing the essential raw materials. Finally, Marler *et al.* teach that the crystal may or may not be made to include aluminum (column 5, lines

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12-20). Because each of the limitations set forth in the claims is taught by Marler *et al.*, the compositions comprising silica taught by Marler *et al.* anticipate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Newly amended claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorn (US Patent 4,927,750) in view of Young (US Patent 3,846,337).

Claims 1 is drawn to a composition comprising silica having an average size of 6 microns or less, and dependent claims 2 define possible types of silica, dependent claim 9 is directed to a silica composition which does not contain aluminum, and dependent claim 10 describes further

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modifications of the composition and that the silicate has pores. At the time of the claimed inventions various forms of silicates were known and described. Dorn *et al.* describe a composition comprising silica with the preferred particle size of about 30-220 angstroms (column 2; lines 15-17) and as large as 600 angstroms (column 6; line 66). It is taught that the silica compositions can be further modified by coating the particles with a variety of polymers each which would uniquely affect the property of the silica particle (column 2; lines 26-42). Dorn teach that some silica themselves are toxic to certain cell types and attempts have been made to reduce the toxicity (column 2, lines 23-26). In one case aluminum was chemically incorporated into the silica (column 2; lines 57-68). In summary, the compositions taught by Dorn can be designed to be non-toxic to cells and used to isolate living cells, and therefore, can be used in other forms of pharmaceutical compositions. Each of the structural limitations set forth in the claims for the silicate are taught by Dorn except that the silicates which are used are in crystalline form. At the time of filing crystalline forms of silicates were well known. Young teaches methods and compositions for generating crystalline silicates. In particular, Young teaches that the disclosed methods can be used to generate improved silicate composite compositions having a high resistance to compressive forces (column 2, lines 47-55 and column 5, lines 27-30 for example). Further, Young teaches that the silicates can be used in colloidal compositions (column 4, lines 6-67) such as those taught in Dorn. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make and use silicates which are in crystalline form. One having ordinary skill in the art would have been

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motivated to use the methods discussed in Young to make the silicates taught by Dorn because the silicates of Young represent improved composites which can withstand greater compressive forces. As taught by Dorn, the silicates can be used in cell separation methods using centrifugation and one of skill in the art would be motivated to use silicates which can better withstand the compression forces during centrifugation. Various forms of silicates were well known at the time of filing and there would have been a reasonable expectation of success to combine the teachings of both references to use or adapt the methods for preparing crystalline silicates as taught by Young for use in the methods of Dorn.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

With respect to arguments presented in traverse of Dorn, it is noted that Dorn teaches the use of colloidal compositions, however the present claims encompass this type of composition. The limitation of 'comprising a solid silicate' only describes the silicate, which in itself is a solid. Further, a silicate 'in crystalline or semicrystalline form' only describes the nature of the silicate in the composition. This limitation does not limit the nature of the composition itself to any unique type of composition, only that the composition comprise a silicate in crystalline form, versus for example a composition which is uniquely a crystallized powder.

Conclusion

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach



DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 18007630